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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,452	02/25/2002	Stefan Anker	101195-65	1403

27387 7590 03/24/2004

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EXAMINER	
BELYAVSKYI, MICHAIL A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,452	ANKER ET AL.	
	Examiner	Art Unit	
	Michail A Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Restriction

Applicant's amendment, filed 10/19/01 is acknowledged.

Claims 1-22 are pending.

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted:

I. Claims 5, 6 and 19 drawn to a method of treating or ameliorating body wasting or cachexia, comprising administering to the patient an effective amount of a compound that is able to reduce the production, absorption and /or the effect of endotoxin, wherein the compound is a bile acid.

II. Claims 7 and 19 drawn to a method of treating or ameliorating body wasting or cachexia, comprising administering to the patient an effective amount of a compound that is able to reduce the production, absorption and /or the effect of endotoxin, wherein the compound is LPS binding protein.

III. Claims 8 and 19 drawn to a method of treating or ameliorating body wasting or cachexia, comprising administering to the patient an effective amount of a compound that is able to reduce the production, absorption and /or the effect of endotoxin, wherein the compound is bactericidal/permeability increasing protein.

IV Claims 9 and 19 drawn to a method of treating or ameliorating body wasting or cachexia, comprising administering to the patient an effective amount of a compound that is able to reduce the production, absorption and /or the effect of endotoxin, wherein the compound is lopoprotein.

V. Claims 10 and 19 , drawn to a method of treating or ameliorating body wasting or cachexia, comprising administering to the patient an effective amount of a compound that is able to reduce the production, absorption and /or the effect of endotoxin, wherein the compound is combination of LPS binding protein and lipoprotein.

VI. Claims 11-12 and 19 , drawn to a method of treating or ameliorating body wasting or cachexia, comprising administering to the patient an effective amount of a compound that is able

to reduce the production, absorption and /or the effect of endotoxin, wherein the compound is an antibody capable of binding to endotoxin.

VII. Claims 13 and 19 , drawn to a method of treating or ameliorating body wasting or cachexia, comprising administering to the patient an effective amount of a compound that is able to reduce the production, absorption and /or the effect of endotoxin, wherein the compound is an antibody capable of binding to a soluble CD14 receptor.

VIII. Claims 14 and 19 , drawn to a method of treating or ameliorating body wasting or cachexia, comprising administering to the patient an effective amount of a compound that is able to reduce the production, absorption and /or the effect of endotoxin, wherein the compound is a soluble CD14 receptor.

IX. Claims 15 and 19 , drawn to a method of treating or ameliorating body wasting or cachexia, comprising administering to the patient an effective amount of a compound that is able to reduce the production, absorption and /or the effect of endotoxin, wherein the compound is a drug, blocking effectively signaling through toll-like receptor.

X. Claims 16 and 19 drawn to a method of treating or ameliorating body wasting or cachexia, comprising administering to the patient an effective amount of a compound that is able to reduce the production, absorption and /or the effect of endotoxin, wherein the compound is colostrums.

XI. Claim 17, drawn to a method of treating or ameliorating body wasting or cachexia, comprising administering to the patient an effective amount of a compound that is able to reduce the production, absorption and /or the effect of endotoxin, wherein the compound is able to inhibit the response by the cell to endotoxin.

XII. Claim 18, drawn to a method of treating or ameliorating body wasting or cachexia, comprising administering to the patient an effective amount of a compound that is able to reduce the production, absorption and /or the effect of endotoxin, wherein the compound is able to decrease the cytokine production by a cell in response to endotoxin.

Claims 1-4 and 20 -22 are linking claims and will be examined along with claims of the one of the elected Group I-XII.

3. The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

As was also found in the International Search Report, the Invention of Group I was found to have no special technical feature that defined the contribution over the prior art of Sasatomi et al., (J of Hepatology, 1998, 29, 409-416)

Sasatomi et al., teach that the bile acid UDCA has a beneficial effects on treating disease associated with endotoxin. Sasatomi et al., teach that UDCA has beneficial effects on endotoxin metabolism in liver disease and show a parallel between cachexia and immune activation.

Since Applicant's Inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

Species Election

2. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

3. If Groups I-XII are elected, applicant is required to elect a specific method of treating or ameliorating body wasting or cachexia in a patient , wherein a patient has one specific disease selected from the group recited in claims 1 and 2.

These species are distinct because a specific method of treating or ameliorating body wasting or cachexia in a patient , wherein a patient has one specific disease selected from the group recited in claims 1 and 2 differ with respect to specific pathological conditions , etiologies and therapeutic endpoints thus each condition represents patentably distinct subject matter.

In addition,

4. If Group I is elected applicant is required to elect a specific method of treating or ameliorating body wasting or cachexia in a patient , wherein specific bile acid is selected from the group recited in claim 6.

These species are distinct because a specific method of treating or ameliorating body wasting or cachexia in a patient , wherein bile acid is selected from the group recited in claim 6 differ with respect to the structure, physicochemical properties and mode of action . The examination of species would require different searches in the scientific literature.

5. If Groups II or V are elected applicant is required to elect a specific method of treating or ameliorating body wasting or cachexia in a patient , wherein specific lipoprotein is selected from the group recited in claim 9.

These species are distinct because a specific method of treating or ameliorating body wasting or cachexia in a patient , wherein specific lipoprotein is selected from the group recited in claim 9 differ with respect to the structure, physicochemical properties and mode of action. The examination of species would require different searches in the scientific literature.

6. If Group IX is elected applicant is required to elect a specific method of treating or ameliorating body wasting or cachexia in a patient , wherein specific toll-like receptor is selected from the group recited in claim 15.

These species are distinct because a specific method of treating or ameliorating body wasting or cachexia in a patient , wherein specific toll-like receptor is selected from the group recited in claim 15 differ with respect to the structure, physicochemical properties and mode of action . The examination of species would require different searches in the scientific literature.

7. If Group X is elected applicant is required to elect a specific method of treating or ameliorating body wasting or cachexia in a patient , wherein specific colostrums is selected from the group recited in claim 16.

These species are distinct because a specific method of treating or ameliorating body wasting or cachexia in a patient , wherein specific colostrums is selected from the group recited in claim 16 differ with respect to the structure, physicochemical properties and mode of action . The examination of species would require different searches in the scientific literature

8. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

A telephone call was made to Bruce S Londa on 3/12/04 to request an oral election to the above restriction requirement, but did not result in an election being made.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/ 272-0840 The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841 .

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michail Belyavskyi, Ph.D.
Patent Examiner
March 22, 2004

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